K123299

JAN 18 2013

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St. Jude Medical
Neuromodulation Division
6901 Preston Road
Plano, TX 75024 USA
Tel 972 309 8000
Fax 972 309 8150

6.0 510(k) Summary

Contact Information

Owner/Operator:	St. Jude Medical, Inc., Neuromodulation Division
Submitter's Name:	Terrina Wilder, RAC
Address:	6901 Preston Rd., Plano, TX 75024
Telephone Number:	(972) 309-8115 (Office) (972) 309-8265 (Fax)
Date:	October 19, 2012

Device Names

Trade Names:	MTS™ System Wide-Spaced Quattrode™ Percutaneous Lead Wide-Spaced Quattrode™ Percutaneous Trial Lead
Common or Usual Names:	MTS™ System Wide-Spaced Quattrode™ Percutaneous Lead Wide-Spaced Quattrode™ Percutaneous Trial Lead
Classification:	Class II
Classification Names:	Stimulator, Spinal Cord, Implanted for Pain Relief (21 CFR 882.5880) Stimulator, Peripheral Nerve, Implanted for Pain Relief (21 CFR 882.5870)
Predicate Device Names:	MTS™ Multiprogram Trial Stimulator System (K033757) Wide-Spaced Quattrode™ Leads (K072462)

Establishment Registration Number: 1627487

Device Description

MTS™ System

The MTS™ System (also called the Multiprogram Trial Stimulator) is a multi-programmable device designed to deliver low intensity electrical impulses to nerve structures in the dorsal aspect of the

spinal cord. The system consists of an external stimulator, one or two trial cables, and a single or multiple percutaneous trial lead.

The trial stimulator is a battery-powered device that can be worn by the patient and is intended to deliver targeted paresthesia to single or multiple painful sites for trial stimulation either intra-operatively or post operatively for a maximum of 30 days. The device contains electronic circuitry that combines the function of a receiver and a transmitter and allows the stimulator to be easily programmed to deliver electrical pulses via sixteen output polarities through the trial cable to the implanted lead. The Trial Stimulator communicates via an RS232 port with the Rapid Programmer.

Wide-Spaced Quattrode™ Trial and Permanent Leads

The wide-spaced Quattrode trial and permanent leads are for use in spinal cord stimulation and peripheral nerve stimulation. Each lead consists of a variety of platinum iridium electrodes on the distal end connected by individually insulated wires to platinum iridium contact bands on the proximal end. The insulated wires are covered by a biocompatible polyurethane or silicone rubber sheath. The lead assembly consists of 4 cylindrical electrodes spaced at precise intervals. These leads are designed for introduction into the epidural space using an epidural needle, a guide wire, the optional Introde-AK (Introde) lead introducer, and a stylet to aid in positioning. Also, the permanent wide-spaced Quattrode leads (model #s: 3161, 3163, 3166 and 3169) are designed to be placed directly on or adjacent to a peripheral nerve. The exception is found with the wide-spaced Quattrode trial leads (model #3066) in that they are used during a trial implantation period not to exceed 30 days.

Indications for Use Statements

MTS™ System

The Multiprogram Trial Stimulator System is indicated for the treatment of chronic pain of the trunk and limbs, either as the sole mitigating agent or as an adjunct to other modes of therapy used in a multidisciplinary approach.

The Multiprogram Trial Stimulator is intended to be used with St. Jude Medical Neuromodulation Division percutaneous trial leads and external test extensions to deliver paresthesia to single or multiple painful sites for trial stimulation either intraoperatively or postoperatively for up to a maximum of 30 days.

Wide-Spaced Quattrode™ Percutaneous Leads

The St. Jude Medical Neuromodulation Division neurostimulation systems are indicated for spinal cord stimulation (SCS) in the treatment of chronic pain of the trunk and limbs, either as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach.

St. Jude Medical Neuromodulation Division percutaneous leads model number 3066, 3166, 3163, 3166, 3169, extension model numbers 3382, 3383, 3341, 3342, 3343, and receiver model number 3408, transmitter model number 3508, and antenna model numbers 1220 and 1230 are also indicated to stimulate electrically peripheral nerves to relieve severe intractable pain.

The intended uses for the MTS™ System and the Wide-Spaced Quattrode™ Percutaneous Leads are the same as the predicate devices. The proposed change to replace the demand-type pacemaker contraindication does not affect the safe and effective use of the medical devices.

Technological Characteristics

Summary of Non-clinical Studies

Non-clinical data performed to support previous submissions would still be applicable and would support this submission as well. As an effort to evaluate the continued safety and effectiveness of the medical devices mentioned in this submission, a risk evaluation was conducted. Identified risks were mitigated by replacing the contraindication for demand-type pacemakers with a warning statement instructing clinicians to verify that there is no interference between the implantable devices intraoperatively and to avoid a unipolar programming mode.

Summary of Clinical Studies

A clinical evaluation was performed on the MTS™ System which includes associated accessory devices such as leads. This evaluation provides evidence to support the replacement of the contraindication for demand-type cardiac pacemakers with a warning that provides the clinician with mitigators to reduce the risk of spinal cord stimulation (SCS) interference with cardiac device functionality in patients with concomitant systems. The evidence to support this change includes prospective clinical evidence, a systematic literature review, and complaint data analysis.

Conclusion

As a result of the non-clinical and clinical data demonstrated that the MTS™ System and the Wide-Spaced Quattrode™ Leads are as safe, effective and perform as well as the legally marketed devices identified in this 510(k) summary.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

January 18, 2013

St. Jude Medical, Inc., Neuromodulation Division
Terrina Wilder, RAC
Senior Regulatory Affairs Specialist
6901 Preston Rd.
Plano, TX 75024

Re: K123299
Trade/Device Name: MTS Wide-Spaced Quattrode Percutaneous Leads
Regulation Numbers: 21 CFR 882.5880
Regulation Name: Stimulator, Spinal Cord, Implanted for Pain Relief
Stimulator, Peripheral Nerve, Implanted for Pain Reliefs
Regulatory Class: Class II
Product Code: GZB, GZF
Dated: October 19, 2012
Received: October 23, 2012

Dear Ms. Terrina Wilder:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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5.0 Indications for Use

510(k) Number (if known):

Device Name: **MTS™ System**

Indications for Use:

The Multiprogram Trial Stimulator System is indicated for the treatment of chronic pain of the trunk and limbs, either as the sole mitigating agent or as an adjunct to other modes of therapy used in a multidisciplinary approach.

The Multiprogram Trial Stimulator System is intended to be used with St. Jude Medical Neuromodulation Division percutaneous trial leads and external test extensions to deliver targeted paresthesia to single or multiple painful sites for trial stimulation either intraoperatively or postoperatively for up to a maximum of 30 days.

Prescription Use _____ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joyce M. Whang

Division of Neurological and
Physical Medicine Devices
510(k) Number: K123299

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5.1 Indications for Use

510(k) Number (if known):

Device Name: **Wide-Spaced Quattrode™ Leads**

Indications for Use:

The St. Jude Medical Neuromodulation Division neurostimulation systems are indicated for spinal cord stimulation (SCS) in the treatment of chronic pain of the trunk and limbs, either as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach.

St. Jude Medical Neuromodulation Division percutaneous leads model numbers 3066, 3161, 3163, 3166, 3169, extension model numbers 3382, 3383, 3341, 3342, 3343, and receiver model number 3408, transmitter model number 3508 and antenna model numbers 1220 and 1230 are also indicated to stimulate electrically peripheral nerves to relieve severe intractable pain.

Prescription Use _____ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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